

REMARKS

Upon entry of the foregoing amendments, claims 27, 29, 30, and 34-36 are pending in the application. Claim 27 has been amended for the purposes of correction of a typographical error contained therein. The amendment does not introduce any new matter within the meaning of U.S.C. §132, and the amendments are believed to place the claims in condition for allowance. Therefore, entry of the amendments is respectfully requested.

REJECTION UNDER 35 U.S.C. §103(a)

Claims 4, 28, 38 and 48 are rejected as being unpatentable over Erneta et al. (US 5,854,383) in view of Oberhoffner et al. (US 6,048,947).

Applicants respectfully traverse this rejection. The Examiner has failed to establish a prima facie case of obviousness based on Erneta and Oberhoffer, because the references, when considered alone and in combination, do not teach each and every limitation of the present claims.

The invention according to claim 27 of the present application is drawn to a suture material for surgery comprising one or more filaments having a coating thereon, wherein the coating comprises a bioresorbable polymer, which is formed from a random terpolymer with a completely amorphous structure consisting essentially of glycolide, ε-caprolactone and trimethylene carbonate, wherein the

terpolymer contained glycolide in a portion of 10 to 20 wt. %, with the remainder being ε-caprolactone and trimethylene carbonate in a weight ratio between 30:70 and 70:30, and wherein the terpolymer has a glass transition temperature in the range of -40 to 0°C. Specifically, the terpolymer according to the present application is formed by the simultaneous reaction of the monomers of glycolide, ε-caprolactone and trimethylene carbonate as a random polymer.

Further, the terpolymer of the present invention has a molecular weight of more than 30,000 Daltons, and notably is not require any limitation to low molecular weight due to solubility in common solvents even at high molecular weights. The terpolymer of the present invention has an inert viscosity of 0.7-1.3 dL/g in a solution of 0.5 g/dL hexafluoroisopropanol measured at 25°C. The higher viscosity results in a suture with increased resistance to wear.

In contrast, both Erneta and Oberhoffner disclose segmented triblockterpolymers of the A-B-A type. The block polymers of Erneta and Oberhoffner are each prepared in a multi-step reaction of trimethylene carbonate, caprolactone and glycolide. During a subsequent reaction, the prepolymerized polymer is combined or reacted with another monomer. The result of the processes of Erneta and Oberhoffner is a sequential block polymer, not a random polymer as claimed in the present application.

It is well known from the literature, see attached Encyclopedia of Polymer Science and Engineering, vol. 2, p. 324-325 and Encyclopedia of Polymer Science and Technology, vol. 6, p. 573-574, that significant structural differences exist between the block polymers of Erneta and Oberhoffner and the amorphous, random polymers according to the instant application. Specifically, a block polymer is known in the art as a polymer comprising molecules in which there is a linear arrangement of blocks interlinked by covalent bonds. Further, in the art a block is defined as a portion of a polymer molecule in which the monomeric units have at least one constitutional or configurational feature absent from the adjacent portion. Therefore, it is known in the art that the distinguishing feature of a block polymer is constitutional due to the fact that the blocks comprise units derived from a characteristic species of monomer. See, Encyclopedia of Polymer Science and Engineering, vol. 2, p. 324.

Erneta teaches in Example 1, a triblock copolymer of a prepolymer (block B) comprised of trimethylene carbonate, caprolactone and glycolide, which is further reacted with glycolide (block A) alone. Accordingly, the prepolymer is an intermediate used in the production of the block polymer. Erneta gives no direction and provides no teaching as to the properties or potential utility of the intermediate prepolymer.

The Erneta block copolymer may be used as a suture material and as a coating material. The Erneta block copolymers to be used as coatings have a low molecular

weight between 20,000 and 30,000 g/mol (col. 4, lines 1-6) and an inert viscosity of 0.15-0.75 dL/g in a solution of 0.1 g/dL hexafluoroisopropanol measured at 25°C (col. 5, liens 38-42), which is considerably higher than that of the present application. Furthermore, the Erneta polymers have a low degree of crystallinity as taught at col. 2, lines 29-35, rather than being completely amorphous as required by the present claims.

Finally, the mole percentages of the Erneta terpolymer comprise 2-40% trimethylene carbonate and 2-40% caprolactone resulting in a glycolide amount between a minimum of 20% and a maximum of 96%, whereas the present claims require a glycolide concentration of 10-20%.

As such, Erneta fails to teach the amorphous, random polymers claimed in present application. In contrast, Erneta teaches polymers with a low degree of crystallinity even at low molecular weights. When preparing a coating material, Erneta relies on the block polymer structure having a low molecular weight. Accordingly, Erneta provides no motivation to one of skill in the art to use the teachings of Erneta to produce the suture material of the present invention.

Oberhoffner fails to remedy the deficiencies of Erneta. Oberhoffner discloses a segmented triblock terpolymer for use in the preparation of medical devices. The physical characteristics of the polymer do not evidence their use as a coating material nor do the actual teachings of Oberhoffer disclose or suggest use of the polymer as a

coating. Furthermore, the suture material disclosed in Oberhoffner is a solid polymer adapted to be formed to filaments by an extruder.

Based upon the foregoing, each and every limitation of the claims of the present application is not taught. Neither reference shows a completely amorphous random terpolymer for use as a suture coating material. Furthermore, the references alone and in combination provide no motivation or reasonable expectation of success that modification of the teaching contained therein would lead one of skill in the art to arrive at the coatings as presently claimed.

CONCLUSION

Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the rejections. Favorable action with an early allowance of all claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if he has any questions or comments.

Respectfully submitted,

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Date: October 28, 2005



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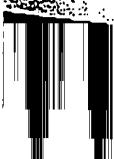
VOLUME 2

Anionic Polymerization
to
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BLOCK COPOLYMERS

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Block copolymers are defined as having a linear arrangement of blocks of varying monomer composition (1). That is, a block copolymer is a combination of two or more polymers joined end-on-end. Star-block or radial block copolymers have branched structures and are not considered here (see BRANCHED POLYMERS). Graft copolymers (qv), although their properties might be similar to those of block copolymers if the number of grafts is limited, are also discussed in a separate article (see also POLYESTERS, ELASTOMERIC; POLYURETHANES, BLOCK COPOLYMERS; STYRENE-DIENE BLOCK COPOLYMERS).

The increasing importance and interest in block copolymers arises mainly from their unique properties in solution and in the solid state which are a consequence of their molecular structure. In particular, sequences of different chemical composition are usually incompatible and therefore have a tendency to segregate in space. Amphiphilic properties in solution and microdomain formation in the solid state are directly related to this specific molecular architecture, which can be designed by using existing monomers or polymers (see also COMPATIBILITY; MICROPHASE STRUCTURE; POLYMER BLENDS).

As an indication of interest and activity in block copolymers, more than a thousand patents have been filed between 1976 and 1982, and the U.S. consumption of thermoplastic elastomers, which represents only a part of the total block copolymer production, is expected to be 400,000 metric tons per year by 1985, with a growth of 9%/yr (2,3).

Definitions and Nomenclature

According to recent proposals of the Commission on Macromolecular Nomenclature of IUPAC (4), a block copolymer, or block polymer, is defined as a polymer comprising molecules in which there is a linear arrangement of blocks. A block is defined as a portion of a polymer molecule in which the monomeric units have at least one constitutional or configurational feature absent from the adjacent portions. In a block copolymer, the distinguishing feature is constitutional, ie, each of the blocks comprises units derived from a characteristic species of monomer.

A block copolymer of type (A-A—A-A)—(B-B—B-B) is designated A_k -block- B_m , where k and m are the number of monomer units in each block, and is named poly A -block-poly B . Similarly, a triblock copolymer, A_k - B_m - A_k , is named poly A -block-poly B -block-poly A ; for example, polystyrene-block-polybutadiene-block-polystyrene. If no ambiguity arises, a long dash may be used to designate block connections, as follows: poly A —poly B and poly A —poly B —poly A . The order of citation of the block names corresponds to the order of succession of the

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blocks in the chain as written from left to right.

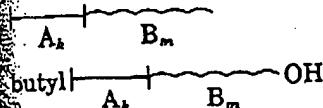
According to earlier IUPAC recommendations and usage (1,5-7), these block copolymers would be designated poly (A-b-B) and poly (A-b-B-b-A). There is no fundamental difference in these nomenclatures for simple structures.

For relatively simple structures, the IUPAC Commission on Macromolecular Nomenclature (4) has also proposed an alternative simplified scheme, which employs the prefix copoly- before the monomer names in parentheses. Another prefix designating the type of copolymer precedes copoly-. For example, block copoly(styrene-butadiene) is a simpler name for polystyrene-block-polybutadiene. This type of copolymer is often designated a styrene-butadiene block copolymer, especially if its structure and sequence arrangement are not specified.

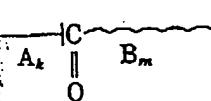
Other structural features of block copolymers can be designated and named as shown by the following examples:

Diblock copolymers

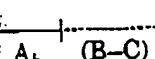
Poly A-block-poly B.



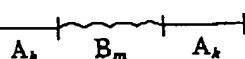
Block copolymer with specified terminal units;
α-butyl-ω-hydroxy-poly A-block-poly B.



Block copolymer with specified junction unit
poly A-block-carbonyl-block-poly B or block co-
poly(A-B)-μ-carbonyl.

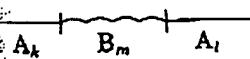


Block copolymer with a second block of B and C monomer units, in which arrangement can be statistical (stat), alternating (alt), or random (ran). The designation with an alternating arrangement of B and C is therefore poly A-block-poly(B-alt-C).

Triblock copolymers

Poly A-block-poly B-block-poly A.

ABA-Tri-block polymer

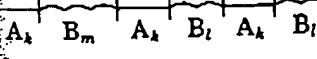


Poly A-block-poly B-block-poly C.

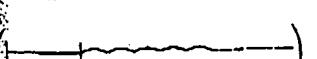
Tri-block polymer



Multiblock copolymers (sometimes designated a segmented block copolymer).



Poly(poly A-block-poly B) or, if $n = 3$, tris(poly A-block-poly B).



Poly(poly A-block-poly B-block-poly C), with statistical arrangement of the sequences poly(poly A-stat-poly B-stat-poly C).

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VOLUME 6

Enzymes
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Library of Congress Catalog Card Number: 64-22188

Printed in the United States of America

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FIBERS, ELASTOMERIC

Elastomeric fibers are characterized by a very high elongation at break (several hundred percent), very low modulus, and high recovery from large deformations. The combination of these properties differentiates elastomeric fibers from stretchable hard fibers which lack some of these features. For example, cold-drawable hard fibers may have high elongation, but there is little or no recovery from large deformations. Crimped hard fibers, on the other hand, never quite reach the high break elongations of elastomeric fibers, and, more importantly, have low recovery forces, which prevent complete and instantaneous recovery where there are frictional forces to overcome, such as in fabrics.

Until recently, elastomeric fibers were made exclusively from rubber, either by slitting prevulcanized sheets (cut rubber), or by extruding compounded rubber mixtures and vulcanizing the thread in an aftertreatment. In this age of completely synthetic fibers, it was inevitable, however, that chemists would attempt to develop highly elastic fibers with properties better than those of rubber. The years from 1960 to 1965 saw a spectacular development of such synthetic elastomeric fibers, causing not only substantial displacement of rubber from traditional markets, but also diversification of elastomeric fibers into whole new areas of technology and uses of stretch fabrics. The most important of these synthetic fibers belong to the class of the spandex fibers. The generic name "spandex" applies to elastomeric fibers with a composition of at least 85% segmented polyurethane (1). This structure and the unique properties it imparts, which have made the recent elastomeric fiber developments possible, will be emphasized in this article.

Chemical Composition

From the standpoint of chemical composition there are three classes of elastomeric fibers: rubber, segmented polyurethanes, and other synthetic copolymers.

Rubber. Rubber fibers are made from a high-quality rubber, such as natural rubber or polyisoprene, which gives the required high tensile strength by its capacity for crystallizing when stretched. Noncrystallizing rubbers, such as styrene-butadiene copolymers, are too weak to be used, especially since reinforcement with carbon black cannot be tolerated in textile uses because of the resulting black color. For detailed descriptions, see the articles RUBBER, NATURAL and ISOPRENE POLYMERS.

Segmented Polyurethans. The chemistry of the segmented polyurethanes of which the spandex fibers are composed is largely isocyanate chemistry (see POLYURETHANS). However, the segmented feature which is very important for the spandex structure makes use of some other aspects of polymer chemistry as well. A segmented polymer is a block copolymer (see BLOCK AND GRAFT COPOLYMERS) in which blocks of distinctly different character alternate; these different blocks or

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segments in spandex fibers are called "soft" and "hard" segments. The urethan bonds are used mainly to tie the segments together, but may also occur in the segments themselves.

Two classes of polymers are used for the soft segment, namely, polyesters (qv) and polyethers (qv). The materials involved are low-molecular-weight polymers (in the 1000-4000 molecular-weight range) with hydroxyl end groups. These so-called "macroglycols" must have a high degree of the theoretically expected bifunctionality in order to give segmented polymers of high molecular weight. Polyester glycols can be made by condensation of dicarboxylic acids with a slight excess of a glycol or glycol mixture or by polymerization of a lactone (2) with a glycol "initiator." Polyether glycols, on the other hand, are made by ring-opening polymerization of epoxides (see, for example, 1,2-EPOXIDE POLYMERS) or cyclic ethers (3) (see, for example, TETRAHYDROFURAN POLYMERS). Since the macroglycols going into the soft segment constitute the major part of a spandex fiber, the choice of intermediates is important, affecting such properties as elastic behavior, sorption, and hydrolytic and oxidative stability. For example, the melting point of the macroglycols should be low enough for the spandex fiber to be in the rubbery state under ambient conditions, but high enough to allow the stretch-induced crystallization giving high tensile strength.

The next step in building a spandex polymer is to put in the urethan linkages between soft and future hard segments, which is most easily accomplished by reacting the macroglycols with an excess of diisocyanate. The hydroxyl-isocyanate reaction, although discovered more than 100 years ago (4), was not used for making polymers until the late 1930s. It produces urethan bonds in a reaction without by-products, except that excess isocyanate under more drastic conditions may react with the urethan to form allophanate branches (5). The reaction can be accelerated with catalysts, for which basic compounds, such as tertiary amines, and compounds of certain heavy metals, such as tin salts, may be used. The reaction product of the macroglycols with excess diisocyanate is a prepolymer with isocyanate end groups that has a certain molecular-weight distribution. It contains not only the diisocyanate end-capped macroglycol but also coupling products, and free, unreacted diisocyanate as well. This mixture is used in a "chain-extending" reaction to complete the synthesis of the segmented polyurethan. Suitable chain extenders are low-molecular-weight diamines or glycols, which react with the isocyanate groups to form urea and urethan structures, respectively, at least two of which occur in each resulting hard segment. Actually, since the isocyanate-terminated prepolymer usually contains unreacted diisocyanate, many hard segments will contain longer sequences of these hydrogen-bonding sites, ie, the urea and urethan structures; that is, the hard segments can be considered as consisting of low-molecular-weight, but high-melting, polymeric entities. Water can also be used as a chain extender (6), but forms only one urea group for every two isocyanate groups, with carbon dioxide as a useless by-product.

The composition of the hard segments is important since it determines their effectiveness in forming "virtual" crosslinks (7) by way of secondary bonds such as hydrogen bonds, between them. These bonds not only replace the covalent cross-links of conventional vulcanized elastomers, but are responsible for superior physical properties, such as toughness and abrasion resistance (8). Most spandex fibers employ hard segments of the aromatic urea type, prepared from aromatic diisocyanates and aliphatic or aromatic diamines. Preferred diisocyanates are 2,4-diisocyanatotoluene (tolylenediisocyanate) (TDI) and bis(*p*-isocyanatophenyl)methane (MDI).

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